

## § 488.2

perform survey and review functions for Medicare.

*Substantial allegation of noncompliance* means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would affect the health and safety of patients and raises doubts as to a provider's or supplier's noncompliance with any Medicare condition.

*Supplier* means any of the following: Independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; chiropractor; or ambulatory surgical center.

*Validation review period* means the one year period during which CMS conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by the accreditation organization.

[53 FR 22859, June 17, 1988, as amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 57 FR 24982, June 12, 1992; 58 FR 30676, May 26, 1993; 58 FR 61838, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997; 71 FR 68230, Nov. 24, 2006]

## § 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

1128—Exclusion of entities from participation in Medicare.  
1128A—Civil money penalties.  
1814—Conditions for, and limitations on, payment for Part A services.  
1819—Requirements for SNFs.  
1861(f)—Requirements for psychiatric hospitals.  
1861(m)—Requirements for Home Health Services  
1861(o)—Requirements for Home Health Agencies  
1861(z)—Institutional planning standards that hospitals and SNFs must meet.  
1861(ee)—Discharge planning guidelines for hospitals.  
1861(ss)(2)—Accreditation of religious non-medical health care institutions.  
1864—Use of State survey agencies.  
1865—Effect of accreditation.  
1880—Requirements for hospitals and SNFs of the Indian Health Service.  
1883—Requirements for hospitals that provide SNF care.  
1891—Conditions of participation for home health agencies; home health quality.

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1902—Requirements for participation in the Medicaid program.

1913—Medicaid requirements for hospitals that provide NF care.

1919—Medicaid requirements for NFs.

[60 FR 50443, Sept. 29, 1995, as amended at 64 FR 67052, Nov. 30, 1999; 77 FR 67164, Nov. 8, 2012]

## § 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) *Basic rules.* In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must:

(1) Meet the applicable statutory definition in sections 1138(b), 1819, 1832(a)(2)(F), 1861, 1881, 1891, or 1919 of the Act.

(2) Be in compliance with the applicable conditions or long-term care requirements prescribed in subpart N, Q or U of part 405, part 416, subpart C of part 418, part 482, part 483, part 484, part 485, subpart A of part 491, or part 494 of this chapter.

(b) *Special Conditions.* (1) The Secretary, after consultation with the JCAHO or AOA, may issue conditions of participation for hospitals higher or more precise than those of either those accrediting bodies.

(2) The Secretary may, at a State's request, approve health and safety requirements for providers and suppliers in that State, which are higher than those otherwise applied in the Medicare program.

(3) If a State or political subdivision imposes higher requirements on institutions as a condition for the purchase of health services under a State Medicaid Plan approved under Title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a State plan for Old Age Assistance under Title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original Title XVI of the Act), the Secretary is required to impose similar requirements as a condition for payment under Medicare in that State or political subdivision.

[53 FR 22859, June 17, 1988, as amended at 58 FR 61838, Nov. 23, 1993; 77 FR 67164, Nov. 8, 2012]